

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.

THIS PAGE BLANK (USPTO)
THIS PAGE BLANK (USPTO)



(19) Europäisches Patentamt

European Patent Office

Office européen des brevets



(11) Publication number: 0 588 631 A2

(12)

EUROPEAN PATENT APPLICATION

(21) Application number: 93307307.4

(51) Int. Cl.⁵: G01K 13/00, A61B 5/00

(22) Date of filing: 16.09.93

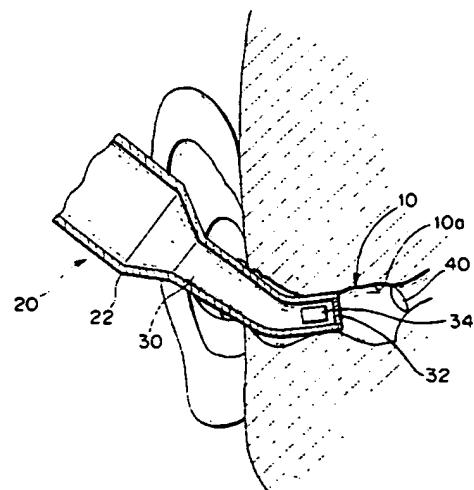
(30) Priority: 17.09.92 JP 247946/92

(72) Inventor: Harada, Hideo
c/o Terumo K.K., 818, Misonodaira
Fujinomiya-shi, Shizuoka-ken (JP)(43) Date of publication of application:
23.03.94 Bulletin 94/12(74) Representative: Harrison, David Christopher
et al
MEWBURN ELLIS 2 Cursitor Street
London EC4A 1BQ (GB)(84) Designated Contracting States:
BE DE FR GB IT NL SE(71) Applicant: TERUMO Kabushiki Kaisha
44-1 Hatagaya 2-chome Shibuya-ku
Tokyo (JP)

(54) Clinical thermometer.

(57) To allow a clinical thermometer for detecting an infrared ray radiated from a tympanic membrane to eliminate thermometric errors caused by personal differences and variations in thermometric operations and to always perform stable, accurate thermometry, there is provided a clinical thermometer for converting infrared radiation from at least one of a tympanic membrane and an external auditory meatus portion near the tympanic membrane into an electrical signal to perform temperature detection, including an almost cylindrical probe body, a constricted diameter portion (30) formed at one end of the probe body and inserted into an external auditory meatus (10) and deformed so as to conform to a shape of the external auditory meatus, and an infrared sensor (34) incorporated in the constricted diameter portion and arranged to direct the tympanic membrane and the external auditory meatus portion near the tympanic membrane.

F I G. 1



EP 0 588 631 A2

The present invention relates to a clinical thermometer used in thermometry for a tympanic membrane and, more particularly, to a clinical thermometer utilizing thermal radiation.

Popular conventional clinical thermometers are for contact type such as axillary or oral thermometry. These clinical thermometers do not necessarily reflect core temperatures of the living body. Thermometry accompanies time restrictions and limitations in terms of thermometric condition, i.e., a rest state, resulting in cumbersome operations.

Since 1960s, tympanic thermometry has received a great deal of attention because it reflects the temperature of the hypothalamus controlling a biological control function. However, methods in those days are dangerous to cause the perforation of a tympanic membrane because a thermocouple or thermistor is directly brought into contact with the tympanic membrane. In addition, thermometry accompanies discomfort and pains. Therefore, tympanic thermometry has not been able to go beyond the range of physiological studies.

In recent years, attempts for detecting an infrared ray radiated from a tympanic membrane to measure a tympanic temperature within a short period of time in a noncontact manner have been made. For example, as disclosed in Japanese Patent Laid-Open No. 61-117422, a noncontact type tympanic thermometer called "First Temp" (tradename) is commercially available from Intelligent Medical Systems, U.S.A. General tympanic thermometry is put into practice.

SUMMARY OF THE INVENTION

An infrared sensor used in the above-mentioned clinical thermometer preferably receives only infrared radiation from a tympanic membrane or an external auditory meatus near the tympanic membrane, which reflects the core temperature of the living body. The material of a constricted diameter portion of a probe inserted into the external auditory meatus to detect a temperature has a large hardness value in a conventional clinical thermometer. The conventional clinical thermometer has a structure having no degree of freedom. It is, therefore, very difficult to receive infrared radiation from the tympanic membrane or the external auditory meatus near the tympanic membrane so as to cause the probe to always conform to the shape of the complicated external auditory meatus which greatly varies depending on different individuals. As a result, the conventional clinical thermometer receives infrared radiation from an outer portion of the external auditory meatus away from vicinity of tympanic membrane and the tympanic membrane.

More specifically, the outer portion of the external auditory meatus away from the vicinity of the tympanic membrane and the tympanic membrane does

not reflect the core temperature of the living body. It is, therefore, very difficult to detect the infrared ray radiated from the tympanic membrane. The temperature of the external auditory meatus is changed by external air or insertion of the probe of the clinical thermometer. As a result, stable, accurate thermometry cannot be performed.

The present invention, therefore, has been made in consideration of the conventional problems described above, and has as its object to provide a clinical thermometer for detecting an infrared ray radiated from substantially a tympanic membrane, capable of always performing stable, accurate thermometry without thermometric errors caused by individual differences in shapes of external auditory meatus and variations in thermometric operations.

It is another object of the present invention to provide a clinical thermometer which can improve directivity of a sensor for receiving an infrared ray in accordance with deformation of a probe and is free from discomfort upon attachment of the clinical thermometer.

In order to achieve the above objects of the present invention to provide a clinical thermometer comprising an infrared sensor for receiving infrared radiation from a tympanic membrane and/or an external auditory meatus near the tympanic membrane and detecting a change in temperature by the infrared radiation as an electrical signal, wherein at least a distal end portion of a probe inserted into the external auditory meatus to perform thermometry is deformed to conform to a shape of an external ear, and directivity of the sensor for receiving an infrared ray follows up the deformation of the probe.

According to the present invention, the degree of freedom includes a degree of freedom obtained by a material and a degree of freedom obtained by a structure and is exemplified by changes caused by bending, elongation/contraction, reciprocal movement, and back-and-forth movement or the like.

The above structure comprises a means for providing a degree of freedom to the shape of the probe inserted into the external auditory meatus to perform thermometry. When the probe is inserted into the external auditory meatus, it is always fitted to conform to the shape of the external auditory meatus which greatly varies depending on different individuals regardless of the shape of the external auditory meatus greatly varying depending on different individuals or an insertion angle for each thermometric operation. The distal end of the probe can be guided in the axial direction of the external auditory meatus. The directivity of the sensor for receiving an infrared ray can follow up the deformation of the probe. Therefore, the probe can be directed in the direction of the tympanic membrane to receive the infrared radiation from the tympanic membrane or the external auditory meatus near the tympanic membrane, thereby eliminating

thermometric errors caused by individual differences and variations in thermometric methods and hence always performing stable, accurate thermometry.

In insertion of the probe into the external auditory meatus, the degree of freedom (right-and-left movement, and back-and-forth movement) is provided to the probe of the clinical thermometer. For this reason, a shock on the wall surface of the external auditory meatus can be minimized to relax pains and discomfort of a patient (an object).

Other features and advantages of the present invention will be apparent from the following description taken in conjunction with the accompanying drawings, in which like reference characters designate the same or similar parts throughout the figures thereof.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a sectional view showing an application state of the main part of a clinical thermometer according to an embodiment of the present invention;

Fig. 2A is a view showing the outer appearance of the main part of a probe portion of the thermometer according to the embodiment shown in Fig. 1;

Fig. 2B is a sectional view of a probe portion of a clinical thermometer according to still another embodiment of the present invention;

Fig. 2C is a view showing the outer appearance of the distal end portion of the probe 20.

Fig. 3 is a view showing the outer appearance of the main part of a probe of a clinical thermometer according to another embodiment of the present invention;

Fig. 4 is a sectional view showing the main part of the probe portion of the clinical thermometer according to the embodiment shown in Fig. 1; and Fig. 5 is a sectional view of a probe portion of a clinical thermometer according to still another embodiment of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Preferred embodiments of the present invention will be described with reference to the accompanying drawings.

Fig. 1 is a sectional view showing an application state of a probe 20 inserted into an external auditory meatus 10 for thermometry of a clinical thermometer as one embodiment. Referring to Fig. 1, a measurement portion is substantially a tympanic membrane 40 including an external auditory meatus 10a near the tympanic membrane 40. The probe 20 comprises comparatively a thick-walled holder portion 22 and a constricted diameter portion 30 extending from the holder portion 22. A hole or window 32 through which

an infrared ray radiated from the tympanic membrane including the external auditory meatus is formed in the distal end portion of the almost cylindrical constricted diameter portion 30. A compact infrared sensor 34 for receiving an infrared ray R radiated from the tympanic membrane including the external auditory meatus is arranged inside the constricted diameter portion 30. The constricted diameter portion 30 preferably has an almost circular cross-section and is tapered toward the distal end thereof. It is also preferable to arrange the infrared sensor 34 inside the distal end portion of the constricted diameter portion 30 to improve measurement precision.

Fig. 2A is a view showing the outer appearance of the probe 20 inserted into the external auditory meatus for thermometry of the clinical thermometer of the embodiment shown in Fig. 1. A material such as a flexible material, an extendible material, or a plastic material (at body temperature) can be exemplified as a material for forming the constricted diameter portion 30 of the probe 20. For example, an elastomer (e.g., soft vinyl chloride or rubber), sponge, or the like can be used. To increase the degree of freedom depending on such a material, a circumferential slit, a bellows, or the like may be preferably formed. The roughness such as jogs, ribs, grooves or the like are preferably disposed in the outer surface of distal end portion of the probe 20 so as to decrease the contacted surface between the probe and the external auditory meatus, thus, the heat transfer between the probe and the external auditory meatus is prevented.

Fig. 4 is a longitudinal sectional view of the probe 20 shown in Fig. 2A. Referring to Fig. 4, the infrared sensor 34 is connected to the distal end of a flexible substrate 38a supported on a rod-like support member 38. The infrared sensor 34 is disposed in the bottom of the recessed portion 34a made of metal such as copper. The recessed portion 34a is preferably sealed by a window member 32. The flexible substrate 38a is surrounded by a coil spring 38c made of copper, bronze, or the like to improve the bending characteristics of the substrate. The predetermined length of a bendable, deformable portion of the constricted diameter portion 30 is preferably about 0 to 12 mm from the distal end of the probe.

Fig. 2C is a view showing the outer appearance of the distal end portion of the probe 20.

It is also preferable to arrange the infrared sensor 34 in or near the distal end portion of the constricted diameter portion 30 to improve the detection precision. The depth of the recessed portion 34a from the bottom thereof to the front of infrared sensor 34 is set enough not to interfere with the angle of view of the infrared sensor 34. A ratio of a depth H of the recessed portion 34a to an inner diameter D thereof preferably falls within the range of 0.05 to 1.0.

Thus, the heat distribution except the object, with in all angle of the view of the infrared sensor 34, can

be small at detecting the infrared from the tympanic membrane. The error by the individual who measures the infrared substantially from the tympanic membrane can be decreased.

A pulse wave detector for detecting a pulse wave and a biological information detecting means for detecting information except for the body temperature, such as a blood pressure oxygen detector for detecting an amount of oxygen can be arranged in a peripheral portion 30a of the external auditory meatus insertion portion of the constricted diameter portion 30.

Fig. 3 shows another embodiment of the present invention which is different from the embodiment of Figs. 2A and 2B in that a material for forming a constricted diameter portion of a probe is a hard material. At least one part 36 of the constricted diameter portion is made of a material such as a flexible material, an extendible material, or a plastic material (at body temperature).

Referring to Fig. 2b, a constricted diameter portion 30 of a probe 40 is made of a flexible material. When the constricted diameter portion 30 is flexed, an infrared sensor 34 is also directed toward the tympanic membrane. For this reason, to increase the heat capacity of an infrared sensor 34, the infrared sensor 39 is supported by an elastic member 39 such as a coil spring supported on a rod-like support member 38. The infrared sensor 34 is directed toward the tympanic membrane so as to follow up bending of the constriction portion. A ball or universal joint may be used in place of the elastic member 39. Only the infrared sensor 34 may be fixed at the distal end portion without using the elastic member 39, a ball joint, or a universal joint.

The elastic member 39 preferably has a high heat-conductivity so as to transfer backward to the heat which is transferred from the external auditory meatus at detecting the infrared from the tympanic membrane and so as to protect the degree of the constricted diameter portion 30 in view of strength.

In a probe shown in Fig. 5, a collar 31 is formed at the proximal end of a relatively non-flexible constricted diameter portion 30. The collar 31 is pivotally mounted in a holder portion 22 of the probe in which the distal end of the collar 31 is stored so as not to be removed from the holder portion 22. Therefore, the constricted diameter portion 30 is pivotal in the 360° forward direction, as indicated by a double-headed arrow W. When the probe is removed from an external auditory meatus, the constricted diameter portion 30 is reset to the initial position by a biasing force of an elastic member 35 such as a coil spring supported on a support member 33. In addition, the constricted diameter portion 30 can be axially withdrawn by the elastic member 35, as indicated by an arrow S.

A light guide tube 37 extending from a window member 32 to the infrared sensor 34 is disposed in

the constricted diameter portion in Fig. 5. An infrared ray R radiated on the window member 32 is guided to the sensor 34. Since the light guide tube 37 is formed integrally with the constricted diameter portion 30, the light guide tube 37 is adjusted to direct toward a tympanic membrane 40 in accordance with the direction of the constriction portion 30. For this reason, an infrared ray representing the temperature of the tympanic membrane can be expected to be incident from the window member 32. The inner wall of the light guide tube 37 is made of a predetermined material which does not absorb, in another words, reflects almost of all the infrared ray, such as gold.

As shown in Fig. 2C, a sensor 34 may be arranged near a window member 32 by a rod-like support member 38 in place of a light guide tube. The rod-like support member 38 is made of the high heat conductivity material, such as copper, copper-alloy (brass), aluminium and aluminium alloy.

As has been described above, according to the present invention, a probe can be accurately inserted into an external ear, and the sensor of the inserted probe is accurately directed toward the tympanic membrane. Therefore, thermometric errors caused by variations in thermometric methods can be eliminated, and stable, accurate thermometry can always be performed.

In insertion of the probe into the external auditory meatus, the degree of freedom (right-and-left movement, and back-and-forth movement) is provided to the probe of the clinical thermometer. For this reason, a shock on the wall surface of the external auditory meatus can be minimized to relax pains and discomfort of a patient. The probe is formed to be ear-phone-type so as to be compact. The probe formed to be headphone type so as to be available as the monitoring system.

As many apparently widely different embodiments of the present invention can be made without departing from the spirit and scope thereof, it is to be understood that the invention is not limited to the specific embodiments thereof.

Claims

1. A clinical thermometer for converting infrared radiation from a tympanic membrane and/or an external auditory meatus portion near the tympanic membrane into an electrical signal to perform temperature detection, comprising:
a substantially cylindrical probe body;
a constricted diameter portion formed at one end of said probe body and inserted into an external auditory meatus and deformed so as to conform to a shape of the external auditory meatus; and
an infrared sensor incorporated in said

constricted diameter portion and arranged to direct the tympanic membrane and the external auditory meatus portion near the tympanic membrane.

2. The thermometer according to claim 1, wherein a portion of said constricted diameter portion which has a predetermined length from an insertion end of said constricted diameter portion is deformable.

3. The thermometer according to claim 1, further comprising a support member extending from an interior of said probe body to an interior of said constriction portion, and an elastic member arranged on a distal end of said support member, said infrared sensor being held in a biased state at a predetermined position between an opening end of said constricted diameter portion and said elastic member.

4. The thermometer according to claim 1, wherein said constricted diameter portion is made of a synthetic resin-based soft material.

5. The thermometer according to claim 1, wherein said constricted diameter portion is made of a sort rubber like material.

6. A clinical thermometer for converting infrared radiation from at least one of a tympanic membrane and an external auditory canal portion near the tympanic membrane into an electrical signal to perform temperature detection, comprising:
 an almost cylindrical probe body;
 a constricted diameter portion formed at one end of said probe body and inserted into an external auditory canal and deformed so as to conform to a shape of the external auditory meatus; and
 an infrared sensor incorporated in said constricted diameter portion, held in a biased state at a predetermined position between a window member and an elastic member by a holding member extending from an interior of said probe body to an interior of said constriction portion, said elastic member arranged at a distal end of said holding means, and said window member disposed in an opening end of said constriction portion, and arranged to be directed toward the tympanic membrane and the external auditory canal portion near the tympanic membrane.

7. The thermometer according to claim 6, wherein said constricted diameter portion is made of a synthetic resin-based soft material.

8. The thermometer according to claim 7, wherein

9. The thermometer according to claim 1, wherein said thermometer further comprising a biological information detecting means for detecting information except for the body temperature, arranged in a peripheral portion of the distal end portion of the probe.

10. The thermometer according to claim 1, wherein said probe comprising an outer surface of a distal end portion thereof formed by roughness.

11. A clinical thermometer for converting infrared radiation from at least one of a tympanic membrane and an external auditory meatus portion near the tympanic membrane into an electrical signal to perform temperature detection, comprising:
 an almost cylindrical probe body;
 a constricted diameter portion arranged to be pivotal through 360° and retractable at one end of said probe body and inserted into an external auditory meatus and deformed so as to conform to a shape of the external auditory meatus; and
 an infrared sensor incorporated in said constricted diameter portion and arranged to direct the tympanic membrane and the external auditory meatus portion near the tympanic membrane.

12. The thermometer according to claim 11, wherein said infrared sensor is arranged near a pivot portion of said constricted diameter portion to guide an infrared ray through a light guide body.

13. The thermometer according to claim 11, wherein said infrared sensor is arranged near a window member incorporated in said constricted diameter portion.

14. The thermometer according to claim 11, wherein said constricted diameter portion is made of a synthetic resin-based soft material.

15. The thermometer according to claim 11, wherein said constricted diameter portion is made of a rubber-based soft material.

16. A clinical thermometer comprising an infrared sensor for receiving infrared radiation from an external auditory meatus and/or a tympanic membrane and detecting a change in temperature by the infrared radiation as an electrical signal, wherein at least a distal end portion of a probe inserted into the external auditory meatus for thermometry is deformed to conform to a

shape of an external ear, and directivity of said infrared sensor for receiving an infrared ray follows up the deformation.

5

10

15

20

25

30

35

40

45

50

55

6

(19)



Europäisches Patentamt

European Patent Office

Office européen des brevets



(11)

EP 0 588 631 A3

(12)

EUROPEAN PATENT APPLICATION

(88) Date of publication A3:
10.07.1996 Bulletin 1996/28

(51) Int Cl. 6: G01K 13/00, A61B 5/00

(43) Date of publication A2:
23.03.1994 Bulletin 1994/12

(21) Application number: 93307307.4

(22) Date of filing: 16.09.1993

(84) Designated Contracting States:
BE DE FR GB IT NL SE

(72) Inventor: Harada, Hideo
Fujinomiya-shi, Shizuoka-ken (JP)

(30) Priority: 17.09.1992 JP 247946/92

(74) Representative: Harrison, David Christopher et al
MEWBURN ELLIS
York House
23 Kingsway
London WC2B 6HP (GB)

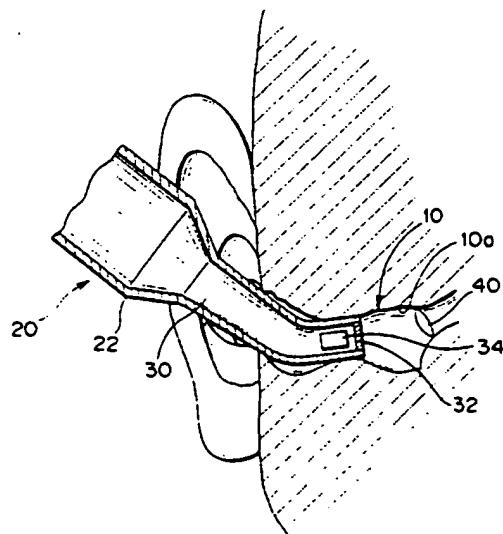
(71) Applicant: TERUMO KABUSHIKI KAISHA
Tokyo (JP)

(54) Clinical thermometer

(57) To allow a clinical thermometer for detecting an infrared ray radiated from a tympanic membrane to eliminate thermometric errors caused by personal differences and variations in thermometric operations and to always perform stable, accurate thermometry, there is provided a clinical thermometer for converting infrared radiation from at least one of a tympanic membrane and an external auditory meatus portion near the tympanic membrane into an electrical signal to perform tempera-

ture detection, including an almost cylindrical probe body (20), a constricted diameter portion (30) formed at one end of the probe body and inserted into an external auditory meatus (10) and deformed so as to conform to a shape of the external auditory meatus (10), and an infrared sensor (34) incorporated in the constricted diameter portion (30) and arranged to direct the tympanic membrane (40) and the external auditory meatus portion (10) near the tympanic membrane (40).

F I G. 1



EP 0 588 631 A3



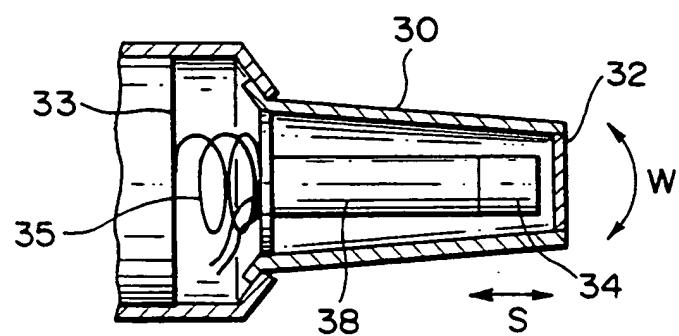
European Patent
Office

EUROPEAN SEARCH REPORT

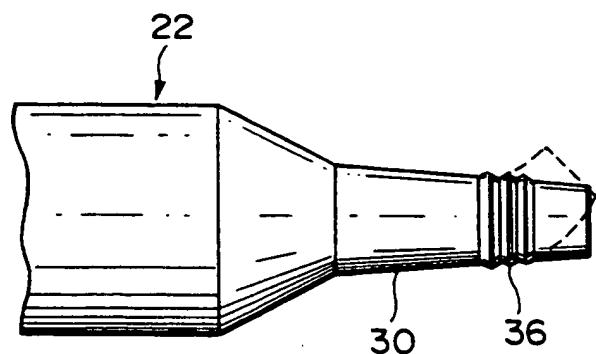
Application Number
EP 93 30 7307

DOCUMENTS CONSIDERED TO BE RELEVANT			CLASSIFICATION OF THE APPLICATION (Int.Cl.5)
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	
X	US-A-3 581 570 (WORTZ EDWARD C) 1 June 1971 * column 2, line 64 - column 4, line 69; figures *	1,4,5,10	G01K13/00 A61B5/00
X	EP-A-0 461 068 (METRAUX GILBERT) 11 December 1991 * the whole document *	1-5	
A	US-A-5 018 872 (SUSZYNSKI EDWARD D ET AL) 28 May 1991 * abstract; figures 6,7 *	1,4,5,10	
			TECHNICAL FIELDS SEARCHED (Int.Cl.5)
			G01K G01J
The present search report has been drawn up for all claims			
Place of search	Date of completion of the search	Examiner	
THE HAGUE	25 April 1996	Ramboer, P	
CATEGORY OF CITED DOCUMENTS		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date U : document cited in the application I : document cited for other reasons d : member of the same patent family, corresponding document	
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document			

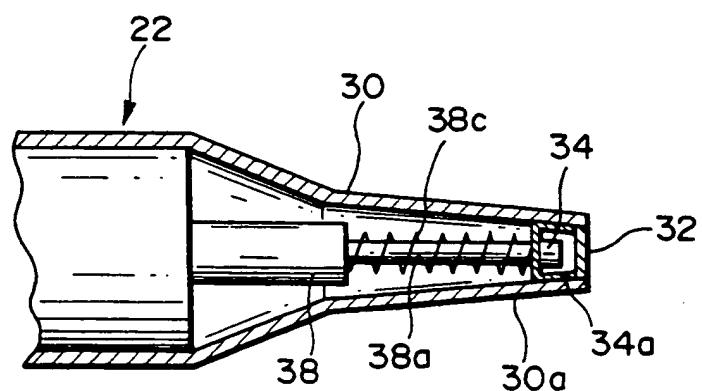
F I G. 2C



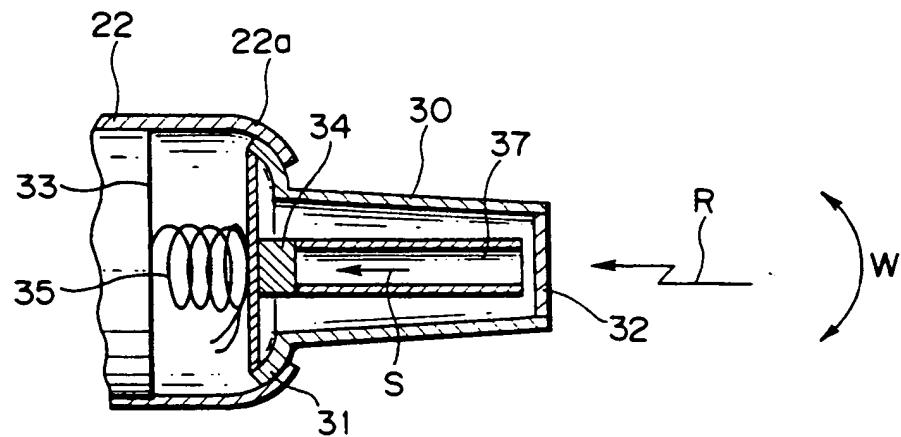
F I G. 3



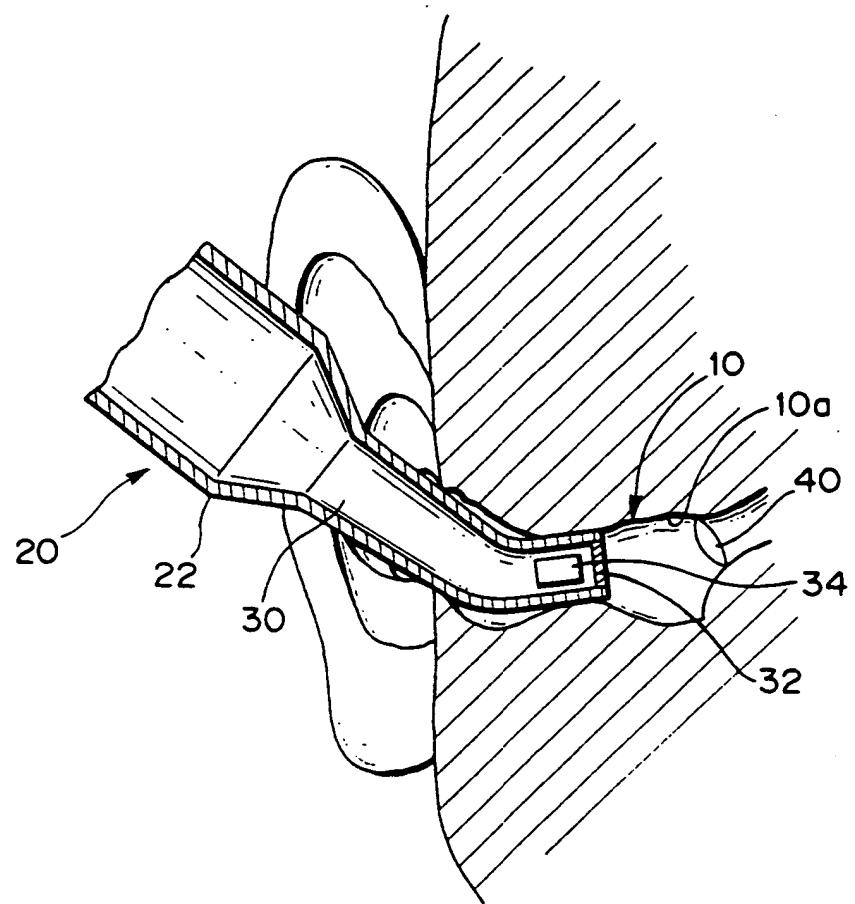
F I G. 4



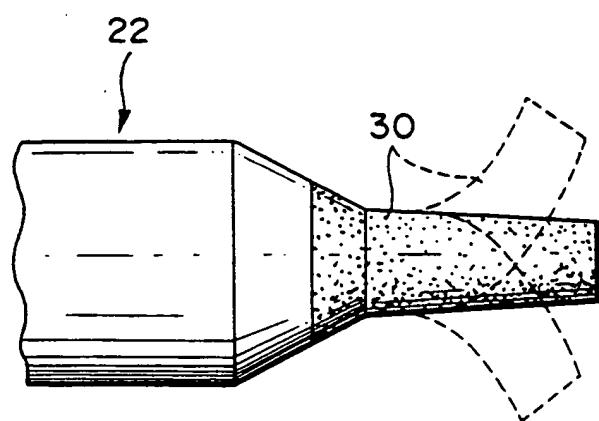
F I G. 5



F I G. 1



F I G. 2A



F I G. 2B

